FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

	Hon. Faith S. Hochberg, U.S.D.J.
	MDL No. 1479 Master File No. 02-1390
IN RE NEURONTIN ANTITRUST LITIGATION	**OPINION & ORDER**
	Date: August 10, 2011

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HOCHBERG, District Judge:

This matter comes before the Court upon Class Plaintiffs' Motion for Discovery Pursuant to the Crime-Fraud Exception to Attorney-Client Privilege. Plaintiffs seek in camera review of documents deemed privileged by Defendants Pfizer, Inc. and Warner-Lambert Company LLC (collectively, "Pfizer") in order to determine whether the crime-fraud exception applies. The Court has considered the written submissions of the parties and held oral argument on the motion on May 5, 2010.

BACKGROUND

Plaintiffs in the instant action directly purchased Neurontin, a brand-name version of the drug compound gabapentin anhydrous from Defendants. In their Amended Complaint, Plaintiffs allege that Pfizer engaged in an overarching anti-competitive scheme to acquire and maintain monopoly power in the market for gabapentin products in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.[1]

Plaintiffs claim that these actions were designed to, and did, in fact, delay the entry of generic gabapentin into the market until late 2004. Plaintiffs allege that but for Pfizer's anti-competitive scheme, generic manufacturers would have entered the market at lower prices as early as 2000. As a result of this delayed entry, Plaintiffs contend that they and other direct purchasers of Neurontin were foreclosed from the opportunity of purchasing lower-priced generic

[1] Pfizer is alleged to have carried out this scheme by: (1) procuring two additional patents that it improperly listed in the Orange Book; (2) manipulating the patent approval process so that a third patent with claims so limited that they are impossible to accurately measure or distinguish from the prior art enabling the patent to be used to delay generic entry; (3) filing and prosecuting multiple sham lawsuits on these patents that no reasonable litigant could have expected to succeed; and (4) engaging in fraudulent off-label promotion to convince doctors to prescribe Neurontin for uses for which it was not approved.

versions of the drug for years, and were accordingly compelled to pay non-competitive prices for gabapentin.[2]

DISCUSSION

The attorney-client privilege is the oldest confidential communications privilege known to the common law. United States v. Zolin, 491 U.S. 554, 562 (1989). The purpose of the privilege is to:

> encourage the full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice. The privilege recognizes that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer's being fully informed by the client.

Upjohn Co. v. United States, 449 U.S. 383, 389 (1981).

"It is the purpose of the crime-fraud exception to the attorney-client privilege to assure that the seal of secrecy between lawyer and client does not extend to communications made for the purpose of getting advice for the commission of a fraud or crime." Zolin, 491 U.S. at 563 (internal quotations omitted).

Typically, application of the crime-fraud exception begins with "presentation of the factual basis for a good faith belief that the exception would apply," followed by "in camera evaluation of the material by the court," and provision of an opportunity to be heard to the party opposed to disclosure. Prudential Ins. Co. of Am. v. Massaro, 47 Fed. Appx. 618 (3d Cir. 2002) (citing Haines v. Liggett Group, Inc., 975 F.2d 81, 96-97 (3d Cir. 1992)).

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[2] The background of the instant litigation was set forth in detail in the Court's Opinions dated August 27, 2009, deciding Pfizer's motion to dismiss, and dated January 25, 2011, granting Plaintiffs' motion for class certification. The Court presumes familiarity with the facts and arguments summarized in those Opinions as well as the abbreviations and acronyms used therein.

"[T]he decision to engage in in camera review implicates a much more lenient standard of proof than the determination to apply the crime/fraud exception...." Haines, 975 F.2d at 96 (internal quotations omitted). In order for a court to engage in in camera review, the party seeking must show "a factual basis adequate to support a good faith belief by a reasonable person that in camera review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies." Id.

Once the documents are before the court for in camera review, the party invoking the crime-fraud exception must make "a prima facie showing that (1) the client was committing or intending to commit a fraud or crime and (2) the attorney-client communications were in furtherance of that alleged crime or fraud." In re Grand Jury Subpoena, 223 F.3d 213, 217 (3d Cir. 2000).

Class Plaintiffs seek in camera review of documents related to (1) the filing of the '479 Patent litigation as part of a profit-protection scheme that included Defendants' off-label marketing of Neurontin and (2) potential fraud or misrepresentation to then Magistrate Judge Chesler and Judge Lifland[3] in the course of this and related patent litigation.[4]

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[3] On March 12, 2007, this action was reassigned to this Court and to Magistrate Judge Shwartz. (Dkt. No. 52)

[4] On May 21, 2010, Class Plaintiffs submitted four lists identifying the documents of which they seek in camera review. (Dkt. No. 343) The first set of documents all fall into one of five categories set forth by Magistrate Judge Shwartz in her March 29, 2010 Order: (1) off label uses and/or off label marketing of Neurontin; (2) Pfizer's July 1, 1999 letter to Judge Chesler in Warner-Lambert v. Purepac & Faulding, No. 98-2749 (JCL); (3) the December 27, 2000 hearing in the same action before Judge Chesler; (4) the summary judgment papers submitted in that action concerning the '479 patent; and (5) statements made concerning off-label marketing at the September 24, 2004 hearing in Warner-Lamber v. Purepac, No. 00-2931 (JCL), before Judge Lifland. The three remaining sets of documents are related to (1) '479 Patent, '479 Patent Case or "Purepac Litigation;" (2) "Off-Label" Litigation; and (3) Neurontin Patents and Neurontin

I. FRAUD OR CRIME

Class Plaintiffs point to two potential bases upon which this Court might find a "fraud or crime" in order to properly invoke the crime-fraud exception after in camera review: (1) Defendants' illegal off-label promotion of Neurontin and the filing of the '479 patent litigation as part of a scheme to create and protect the profits generated by Neurontin and (2) a fraud on the court with regard to statements about Defendants' off-label promotion.

A. Illegal Off-Label Promotion of Neurontin

Pfizer, as set forth in its own guilty plea, engaged in the illegal off-label promotion of Neurontin between 1995 and 1996. A Massachusetts court recently found, based on lengthy civil trial proceedings, that those illegal activities continued in some cases until December 2004.

As set forth in greater detail below, Class Plaintiffs argue that the filing and prosecution of several lawsuits designed to protect Pfizer's interest in the '479 Patent – the filing of which triggered an automatic stay of the FDA approval process for all generic products for 30 months – were part of a plan by the company to protect the large profit base generated by Neurontin's off-label sales.

1. The Criminal Guilty Plea

On May 13, 2004, a criminal information was filed in Massachusetts, charging Warner-Lambert with distribution of an unapproved new drug in violation of 21 U.S.C. §§ 331(d), 333(a)(2) and 355(a) and with distribution of a misbranded drug in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 352(f)(1). See United States v. Warner-Lambert Co., Crim. No. 04-10150

Patent Litigations and, according to Class Plaintiffs, cannot be evaluated without further information. See Pltf. Second Supplemental Submission at 1.

"Information," (D. Mass. 2004). The Information charged that though Neurontin was approved for use only in epilepsy patients, between April 1995 and August 1996, Warner-Lambert promoted it for a variety of unapproved or "off label" uses, including post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis ("ALS"), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy and migraine headaches.[5]

On June 7, 2004, Pfizer pled guilty to all counts in the Information pursuant to a plea agreement with the Government. As part of that agreement, Pfizer "expressly and unequivocally admit[ted] that it committed the crimes charged in the Information" and agreed "that the facts set forth in the Information are true."[6]

2. Findings of Fact & Conclusions of Law in In re Neurontin Marketing and Sales Practices Litigation

On November 3, 2010, Judge Patti B. Saris of the United States District Court for the District of Massachusetts issued Findings of Fact and Conclusions of Law in In re Neurontin Marketing and Sales Practices Litigation, No. 04 Civ. 10739 (PBS) (D. Mass. Apr. 13, 2004). The opinion dealt specifically with a suit filed by Kaiser Foundation Health Plan and Kaiser Foundation Hospitals alleging that Pfizer violated the Racketeer Influenced and Corrupt Organizations Act and the California Unfair Competition Law. After a five week jury trial, a jury found that "Pfizer engaged in a RICO enterprise that committed mail and wire fraud by fraudulently marketing Neurontin for off-label conditions..." Kaiser Found. Health Plan, Inc. v.

[5] Opper Decl., Ex. 6.

[6] Opper Decl., Ex. 7.

Pfizer, Inc., 748 F. Supp. 2d 34, 38 (D. Mass. 2010). The court found for Kaiser on its Unfair Competition claim as well. Id.

The Kaiser court found that Pfizer had engaged in fraudulent marketing activities – promoting Neurontin to treat bipolar disorder, neuropathic pain and migraines and generally to be taken in doses greater than 1800 mg/day – as recently as December 2004. Id. at 48. Pfizer was found to have "suppressed negative clinical trials and showcased positive ones," "sponsored continuing medical education programs and detailed doctors to promote off-label uses of the drug." Id. at 37. The court also concluded that Pfizer's fraudulent activity included "making material misrepresentations in advertising supplements, articles it sponsored, and direct communications to Kaiser," as well as "showcasing positive information about Neurontin's efficacy in the published literature, while suppressing negative evidence from Pfizer -sponsored clinical trials about Neurontin's efficacy" for off label uses. Id. at 38-39. Finally, the Kaiser court found "little or no scientifically accepted evidence that Neurontin is effective for the treatment of bipolar disorder, neuropathic pain, nociceptive pain, migraine, or [in] doses greater than 1800 mg/day." Id. at 39.

B. Conduct in Related Patent Litigation

Despite later acknowledging its illegal conduct, Warner-Lambert repeatedly denied having engaged in off-label promotion to the court presiding over Warner-Lamber v. Purepac & Faulding, No. 98-2749 (JCL), an action in which Warner-Lamber alleged infringement by generic pharmaceutical companies of the '479 Patent.

In a July 1, 1999 letter to then-Magistrate Judge Stanley R. Chesler addressing a variety of discovery disputes in that action, counsel for Warner-Lambert wrote that, "Warner-Lambert

has never promoted or advertised Neurontin® for any other use other than epilepsy – and it will never do so unless that use becomes approved by the F.D.A."[7]

That year, two of the generic defendants – Purepac and Apotex – moved for summary judgment. In opposing the motions, Warner-Lambert submitted two affidavits indicating that off-label sales were the product of the efficacy of Neurontin for other indications, without acknowledging that any off-label promotion had taken place.[8]

During a December 27, 2000 hearing, Magistrate Judge Chesler asked Warner-Lambert's counsel to confirm that he has "just stated earlier that your view of the record indicates that there is no evidence or no suggestion that there was – or no issue that there was any improper promoting of Neurontin for off-label use with regard to the off label uses that are covered by the patent?"[9] Counsel indicated that Magistrate Judge Chesler's statement accurately reflected his position, responding, "Yes, sir."[10]

It was only after Pfizer entered a guilty plea in Massachusetts that the company acknowledged to the court presiding over the related patent litigations that it engaged in unlawful off-label marketing.[11]

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[7] Opper Decl., Ex. 2 at 3.

[8] See Opper Decl., Ex. 17-18. The affidavit of Dr. Elizabeth A. Garofalo, for example, indicates that a number of scientific studies have found gabapentin – the generic name for Neurontin – "to be effective in treating indications other than epilepsy." Oper Decl., Ex. 17 ¶¶ 5-14.

[9] Opper Decl., Ex. 16 at 26:15-26:20.

[10] Id. at 26:21.

[11] See Oper Decl, Ex. 5 at 77 ("The issue was they really shouldn't have gone out and done, been as aggressive as they were over the doctors, and promoting the use of this drug. And

II. COMMUNICATIONS IN FURTHERANCE

To satisfy the "in furtherance of" element of the crime-fraud exception, "a logical link must exist between the privileged communication and the proposed crime or fraud." Prudential Ins. Co. v. Massaro, No. 97 Civ. 2022 (AMW), 2000 U.S. Dist. LEXIS 11985, at *27 (D.N.J. Aug. 14, 2000). That is, the legal advice "must relate to future illicit conduct by the client; it [must be] the causa pro causa, the advice that leads to the deed." Haines, 975 F.2d at 90. Further, "[i]t does not suffice that the communications may be related to a crime; . . . they must actually have been made with an intent to further an unlawful act." United States v. White, 887 F.2d 267, 271 (D.C. Cir. 1989); see also Geoffrey C. Hazard, Jr. & W. William Hodes, THE LAW OF LAWYERING § 1.6:104 at 147 ("the communications must actually contribute to the criminal activity, not merely provide evidence of it").

A. The '479 Patent Litigation

Plaintiffs seek in camera review of a set of communications between Warner-Lambert and its counsel relating to Warner-Lambert's prosecution of actions against several generic drug manufacturers alleging infringement of its '479 patent. Specifically, Plaintiffs seek the communications between Warner-Lambert and its counsel concerning the basis for filing and prosecuting the '479 patent litigation. Plaintiffs argue that:

> In order to protect the market for off-label sales that it had illegally created, Warner-Lambert filed infringement litigation relating to its '479 patent after its generic competitors had filed ANDAs seeking to market a generic version of Neurontin....By doing so, Warner-Lambert invoked the Hatch-Waxman automatic 30-month stay on FDA approval of the generics' products even for the approved uses. Thus, in filing the '479 infringement actions Warner-Lambert furthered its

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the government stepped in around 1999 and filed their complaint, certainly activities stopped at that time....").

> criminal conduct and maintained its sales in the off-label market it had illegally promoted.

(Pltf. Feb. 19, 2010 Br. at 23)

This Court is deeply troubled by the illegal conduct to which Pfizer admitted in its guilty plea in Massachusetts, as well as by Judge Saris's conclusions about Pfizer's off-label marketing and promotional practices in Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc.. As this Court acknowledged in its June 9, 2011 Opinion & Order, this Court "fully expects" the issue of estoppel based on past admissions and judicial determinations with respect to off-label promotion "will be the subject of a summary judgment or in limine motion as this case proceeds." In re Neurontin Antitrust Litig., No. 02-1390 (FSH), Opinion & Order at *17-18 (D.N.J. June 9, 2011) (Dkt. No. 469).

As disturbing as Pfizer's conduct with respect to off-label promotion of Neurontin is, Class Plaintiffs have not set forth a reasonable basis upon which to conclude that in camera review would demonstrate that communications about the prosecution of the '479 Patent litigation were made with an intent to further unlawful promotion or profit-making schemes involving off-label marketing.

Class Plaintiffs' theory is, at its essence, that both the '479 Patent litigation and Pfizer's off-label marketing were designed to generate greater profits than those the company would legally have gained from Neurontin, and therefore the privileged communications regarding the latter would reasonably reveal acts in furtherance of a crime or fraud involving the former. This theory suffers from two flaws at this juncture. First, Class Plaintiffs' have not presented any basis beyond their own allegations upon which this Court could conclude that Pfizer's

willingness to engage in misconduct with regard to off-label promotion necessarily means that Pfizer filed the '479 Patent Litigation with ulterior motives. Second, the connection between Pfizer's off-label promotion and the filing of the '479 Patent Litigation is simply too attenuated for this Court to form a good faith belief that the two efforts are part of a singular anti-trust scheme. The mere fact that both efforts may have been made in order to wring further profit out of Neurontin is not sufficient. Accordingly, in camera review of the '479 Patent litigation documents is denied at this time.[12] See In re ML-Lee Acquisition Fund II, LP, 848 F. Supp. 527, 566 (D. Del. 1994) (denying motion for discovery pursuant to crime-fraud exception because "mere allegations are not sufficient" to form "requisite factual basis").

B. Representations to the Court

Class Plaintiffs also seek in camera review of documents regarding Pfizer's off-label marketing and subsequent representations to the Court on that subject. They argue that the communications embodied in these documents were made in furtherance of the scheme to hide illegal off-label promotion.

As set forth above, Pfizer made several representations to the court presiding over Neurontin related patent litigation that it was not involved in illegal off-label promotion. Those statements are directly contrary to Pfizer's admission in its 2004 guilty plea and with the court's conclusions in Kaiser Found. Health Plan, Inc. v. Pfizer, Inc.. If the statements made to the court were untrue, Class Plaintiffs are entitled to probe what the speakers knew and what Pfizer knew

[12] While Class Plaintiffs have not satisfied the requisite burden in order to seek in camera review of the '479 Patent litigation documents at this time, this Court does not preclude the possibility that Class Plaintiffs might later renew their application should additional information come to light.

about those speakers' statements. A reasonable person might well conclude that the statements were made as part of a scheme to hide Pfizer's misconduct.[13] The documents Class Plaintiffs seek were prepared in the course of that litigation and are specific to either Pfizer's off-label marketing efforts or its work before the court on specific instances where it appears misrepresentations were made. Taken together, the circumstances surrounding Pfizer's off-label promotion and its representations to the court on the subject provide ""a factual basis adequate to support a good faith belief by a reasonable person that in camera review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies."[14] Haines, 975 F.2d at 96.

CONCLUSION

[13] Indeed, the connection between Pfizer's wrongdoing and its statements to the court is much more clear than under Class Plaintiffs' theory regarding the filing and prosecution of the '479 Patent litigation. Pfizer denied the illegal conduct it later admitted, and that illegal conduct was found to have continued until 2004, despite Pfizers' statements that it ended once the Government's probe began in or about 1999. Additionally, the Massachusetts court makes repeated reference to Dr. Gary A. Mellick, a paid Pfizer consultant who issued several reports about Neurontin's effectiveness in treating conditions other than epilepsy. See Kaiser Found. Health Plan, Inc., 748 F. Supp. 2d at 46, 56, 62, 64. In opposing motions for summary judgment in the patent litigation, Pfizer submitted an affidavit of Dr. Elizabeth A. Garofalo, who cited a study by Dr. Mellick in support of her opinion about Neurontin's efficacy. Oper Decl., Ex. 17 ¶¶ 5-14.

[14] No allegation has been made that the attorneys who made the representations at issue were aware that those representations were false. However, "the crime-fraud exception applies even when an attorney is unaware that the client is engaged in or planning a crime." In re Grand Jury Investigation, 445 F.3d 266, 279 n. 4 (3d Cir. 2006); see also United States v. Doe, 429 F.3d 450, 454 (3d Cir. 2005) ("The crime-fraud exception to the attorney-client privilege applies to any communications between an attorney and client that are intended to further a continuing or future crime or tort. In this analysis, the client's intention controls and the privilege may be denied even if the lawyer is altogether innocent.") (internal quotations omitted).

For the reasons set forth above,

IT IS on this 10th day of August, 2011,

ORDERED that Plaintiffs' Motion for Discovery Pursuant to the Crime-Fraud Exception to Attorney-Client Privilege is **GRANTED** in part and **DENIED** in part; and it is further

ORDERED that Class Plaintiffs are entitled to in camera review of the following categories of documents, as set forth in their May 21, 2010 submission: documents relating to (1) off label uses and/or off label marketing of Neurontin; (2) Pfizer's July 1, 1999 letter to Judge Chesler in Warner-Lamber v. Purepac & Faulding, No. 98-2749 (JCL); (3) the December 27, 2000 hearing in the same action before Judge Chesler; (4) the summary judgment papers submitted in that action concerning the '479 patent; and (5) statements made concerning off-label marketing at the September 24, 2004 hearing in Warner-Lamber v. Purepac, No. 00-2931 (JCL), before Judge Lifland;[15] and it is further

ORDERED that the identified documents shall be submitted to Special Master Rice in accordance with the procedures he has prescribed.

The Clerk of the Court is directed to terminate the motion: Dkt. No. 288.

s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.

[15] The other documents outlined in the May 21, 2010 submission will not be subject to in camera review at this time.